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1644	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/510,655	GROENLUND ET AL.	
	Examiner	Art Unit	
	NORA M. ROONEY	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 July 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *10-23* is/are pending in the application.

4a) Of the above claim(s) *11-14* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10 and 15-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment filed on 07/21/2008 is acknowledged.

2. Claims 11-14 stand withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Groups, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 11/27/2007.

3. Claims 10 and newly added claims 15-23 are currently under examination as they read on a microparticle comprising a bead and a plant pollen allergen.

4. It is noted that the font that Applicant has used for claim amendments filed on 07/21/2008 makes it very difficult for the Examiner to read after scanning into the computer. The Examiner would appreciate it if Applicant would switch to another font for future communications with the Office.

5. The following rejections are necessitated by the amendment filed on 07/21/2008.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claim10 stands rejected and claims 15-23 *are* rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for : a microparticle consisting essentially of Phl p 5b covalently bound to CBP and a medicament thereof, does not provide reasonable enablement for : **a medicament for allergen-specific immunotherapy capable of generating an immunoprotective response,** said medicament containing a therapeutically effective amount of microparticles comprising: (a) **a bead consisting of a three-dimensionally cross-linked carbohydrate selected from the group consisting of polyarylamide, vinyl polymer, dextran, agarose, and mixtures thereof**; and (b) a **polypeptide allergen derived from plant pollen** covalently bound to said bead of claim 15; which is formulated characterized in that it is prepared for parenteral application of claim 10; wherein the carbohydrate bead consists essentially of agarose of claim 16; wherein the carbohydrate bead comprises cyanogen bromide-activated sperical agarose of claim 17; wherein **the allergen is derived from grass pollen** of claim 18; wherein **the grass pollen allergen** is **derived from timothy grass pollen** of claim 19; wherein the timothy grass pollen allergen is the Phl p 5b allergen of SEQ ID NO:1 of claim 20; wherein the particle size ranges from 0.5 μm to 5 μm of claim 21; wherein the particle size ranges from 0.1 μm to 10 μm of claim 22; and wherein the carbohydrate bead comprises cyanogen bromide-activated spherical agarose and the polypeptide allergen comprises the timothy grass pollen allergen Phl p 5b of SEQ ID NO:1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and or use the invention commensurate in scope with this claim for the same reasons as set forth in the Office Action mailed on 02/21/2008.

The specification does not adequately disclose a medicament comprising bead made of "a three dimensionally cross-linked carbohydrate selected from the group consisting of polyarylamide, vinyl polymer, dextran, agarose and mixtures thereof." The specification only disclosed .2 μm cyanogen bromide-activated spherical Sepharose particles (CBP) for use in the claimed invention. The art of Neiman-Anderson et al. (PTO-892; Reference U) teaches that allergen specific non-responsiveness is induced by .2 μm CBP particles because the allergens can be couple to the CBPs with a high density. Therefore, not only is the type of particle used (CBP) important for generation of non-responsiveness, but the size of the particle matters as well. The specification has not adequately disclosed the genus of medicaments encompassed by the instant claims recitation for use in the claimed invention, especially in view of the post-dated art which demonstrates that the properties of the particle are important for generation of non-responsiveness.

The specification also does not adequately disclose any "polypeptide allergen" for use in the claimed invention. The specification has only disclosed Phl p 5b for use in the claimed invention to be covalently bound to CBP. The genus of any polypeptide allergen encompasses any whole allergen or fragments thereof to be coupled to CBP. However, the art of peptide immunotherapy teaches that the structure of the polypeptides and fragments thereof used in immunotherapy matter to the outcome of generating hyporesponsiveness. The specification has not adequately discloed what allergens or portions of allergens of the genus of all polypeptide allergens that can be used to generated a immunoprotective response *in vivo*. Because of the

unpredictability of determining which allergens can be used as a medicament for generating an immunoprotective response and because the specification had not provided guidance or adequately disclosed the genus of allergens that can be used in the claimed invention, one of ordinary skill in the art at the time of invention would not be able to practice the invention commensurate in scope with the claims. The specification fails to provide sufficient enablement for a person of skill in the art to use a medicament comprising any polypeptide allergen bound to any bead "for allergen-specific immunotherapy capable of generating an immunoprotective response."

Applicant's arguments filed on 07/21/2008 have been fully considered, but are not found persuasive.

Applicant argues:

> "The test of enablement is whether one reasonably skilled in the art could make and use the claimed invention from the disclosures in the patent coupled with information known in the art without undue experimentation. The present invention relates to the discovery of the advantageous nature of carbohydrate-based allergen particles over traditional aluminum hydroxide-based allergen particles in the context of allergen-specific immunotherapy. However, as noted in the instant specification (see, for example, p. 5-6), the coupling of polypeptide allergens to carbohydrate-based particles, such as agarose/sepharose beads, uses well-described and reproducible procedures analogous to those conventional in the art of ELISA-based diagnostic protocols. Likewise, the medicaments of the present invention operate in a manner analogous to conventional Alum-adsorbed allergy vaccines, inducing an allergen-specific IgG response similar to that of Alum-based particles[1]. Accordingly, one of ordinary skill in the art would be well versed in the methods of making and using the medicaments of the present invention, without undue experimentation and with predictable results.
>
> As for the Examiner's request for evidence substantiating the present claims to "medicaments" (now, "medicaments for allergen-specific immunotherapy capable of generating an immunoprotective response" as set forth in new claim 15), Applicants respectfully direct the Examiner's attention to the examples of the instant specification. The experimental results presented herein conclusively demonstrate that the microparticles of the present invention elicit immune responses that are comparable, and indeed superior, to that of aluminum hydroxide, without the associated granulomatous tissue reactions. Not only do the carbohydrate-based medicaments of the present invention induce strong IgG1, IgG2a/b, and IgG3 antibody responses in mice, antibodies referred to as "blocking antibodies" for their ability to prevent contact between the allergen and the IgE molecules present in the allergic patient's body, thereby avoiding

> mast cell- and basophil-mediated allergic responses such as cytokine secretion and histamine release[2] but they do so with minimal negative side effects, with predictable efficacy of adsorption, with predictable stability of adsorbents, and without altering the functionality of the bound allergen. Thus, it is readily apparent that the medicaments of the instant invention are suited to allergen specific immunotherapy and are capable of generating an immunoprotective response in the subject to be treated.
>
> In sum, Applicants respectfully submit that the *in vitro* and *in vivo* data presented in the instant specification demonstrate that a reasonable correlation exists between the scope of the claims and the scope of enablement. Accordingly, Applicants submit that one of ordinary skill in the art would be able to practice the invention of the claims 10 and 15-23 without undue experimentation and with a reasonable expectation of success."

It is the Examiner's position that the specification has not adequately disclosed a medicament for allergen-specific immunotherapy capable of generating an immunoprotective response for the reasons set forth *supra*. Further, the art of Neimert-Anderson et al. (PTO-892, Reference U) with common authorship to the instant inventors and published in 2008 teaches that it shows "for the first time that CBPs modulate the immune response, allergic inflammation and AHR when use in the treatment of rFel d 1 sensitized mice." The art of Gronlund et al. (PTO-892 mailed on 02/21/2008) and the instant specification teaches that CBP can be used as an adjuvant in place of Alum because it generates increased antibody any cytokine production over alum without the formation of a granulomatous tissue reacton. Neither the art of Gronlund nor the instant specification teaches that an immunoprotective response is generated.

8. Claims 10 stands rejected and claims 15-23 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant is in possession of: a microparticle consisting essentially of Phl p 5b covalently bound to CBP and a medicament thereof.

Applicant is not in possession of: **a medicament** for allergen-specific immunotherapy capable of generating an immunoprotective response, said medicament containing a therapeutically effective amount of microparticles comprising: (a) **a bead consisting of a three-dimensionally cross-linked carbohydrate selected from the group consisting of polyarylamide, vinyl polymer, dextran, agarose, and mixtures thereof**; and (b) a **polypeptide allergen derived from plant pollen** covalently bound to said bead of claim 15; which is formulated characterized in that it is prepared for parenteral application of claim 10; wherein the carbohydrate bead consists essentially of agarose of claim 16; wherein the carbohydrate bead comprises cyanogen bromide-activated sperical agarose of claim 17; wherein **the allergen is derived from grass pollen** of claim 18; wherein **the grass pollen allergen** is **derived from timothy grass pollen** of claim 19; wherein the timothy grass pollen allergen is the Phl p 5b allergen of SEQ ID NO:1 of claim 20; wherein the particle size ranges from 0.5 μm to 5 μm of claim 21; wherein the particle size ranges from 0.1 μm to 10 μm of claim 22; and wherein the carbohydrate bead comprises cyanogen bromide-activated spherical agarose and the polypeptide allergen comprises the timothy grass pollen allergen Phl p 5b of SEQ ID NO:1 for the same reasons as set forth in the Office Action mailed on 02/21/2008.

Applicant has disclosed only a microparticle consisting essentially of Phl p 5b covalently bound to CBP and a medicament thereof; therefore, the skilled artisan cannot envision all the

contemplated microparticle and medicament possibilities recited in the instant claims. Consequently, conception cannot be achieved until a representative description of the structural and functional properties of the claimed invention has occurred, regardless of the complexity or simplicity of the method.

Applicant's arguments filed on 07/21/2008 have been fully considered, but are not found persuasive.

Applicant argues:

> "In this case, Applicants reiterate that the coupling of polypeptide allergens to carbohydrate-based particles, such as agarose/sepharose beads, is conventional in the art of ELISA-based diagnostic protocols. Applicants further submit that the principle mode of allergen-specific immunotherapy does not depend on the nature of a certain allergen but can be readily and routinely generalized for other peptide allergens. Thus, in the context of the instant invention, the timothy grass pollen allergen Phl p 5b (SEQ ID NO: 1) is indeed representative of the requisite structural and functional properties of the genus of "polypeptide allergens derived from plant pollen". As for the supporting carbohydrate bead, to expedite prosecution, Applicants have amended the claims to require three-dimensionally cross-linked carbohydrate selected from the group consisting of "polyarylamide, vinyl polymer, dextran, agarose, and mixtures thereof". Not only does this genus that finds explicit support in the instant specification (see p. 2, lines 10-12) but Applicants respectfully submit that it is a genus that lacks substantial variation and of which the CBP bead is sufficiently representative of the distinguishing identifying characteristics common to the species encompassed thereby."

It is the Examiner's position that the specification has not adequately described the genus of medicaments for allergen-specific immunotherapy capable of generating an immunoprotective response encompassed by the claims for the reasons set forth *supra*. Further, the art of Neimert-Anderson et al. (PTO-892, Reference U) with common authorship to the instant inventors and published in 2008 teaches that it shows "for the first time that CBPs modulate the immune response, allergic inflammation and AHR when use in the treatment of rFel d 1 sensitized mice" (In particular, page 525, last paragraph) The art of Gronlund et al. (PTO-892 mailed on

02/21/2008) and the instant specification teaches that CBP can be used as an adjuvant in place of Alum because it generates increased antibody any cytokine production over alum without the formation of a granulomatous tissue reaction. Neither the art of Gronlund nor the instant specification teaches that an immunoprotective response is generated. Accordingly, the specification has not described a correlation between the structure of the polypeptide allergen or allergen fragments covalently bound to any bead such that the combination can be used to generate an immunoprotective response *in vivo*. "Possession may not be shown by merely describing how to obtain possession of member of the claimed genus or how to identify their common structural features" Ex parte *Kubin* (83 U.S.P.Q.2d 1410 (BPAI 2007)), at page 16. In this instant case Applicants have not provided any guidance as to what polypeptide allergens and peptides thereof that can be combined with what beads to result in a medicament that will generate an immunoprotective response. "Without a correlation between structure and function, the claim does little more than define the claimed invention by function" *supra*, at page 17. In the instant case, definition by function (generate an immunoprotective response) does not suffice to define the genus of medicaments encompassed because it is only an indication of what the medicament does and what functional properties it has, rather than what it is.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claim 10 stands rejected and claims 15-16 and 18-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Nordvall et al. (PTO-892 mailed on 11/13/2007) for the same reasons as set forth in the Office Action mailed on 02/21/2008.

Nordvall et al. teaches a microparticle comprising timothy pollen (derived from plant and grass pollen) covalently bound to Sepharose beaded agarose (In particular, whole document, page 577, right column, first whole paragraph).

Claim 20 is included in this rejection because timothy grass pollen inherently comprises Phl p 5b. The recitation of SEQ ID NO:1 in claim 20 is inherent in Phl p 5b allergen and adds no patentable weight. Further characterization of a known compound does not make it patentably distinct. See Atlas Powder Co. V. IRECO, 51 USPQ2d 1943 (Fed. Cir. 1999) "Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art... However, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer. " The Court further held that "this same reasoning holds true when it is not a property but an ingredient which is inherently contained in the prior art".

Claims 10 are included in this rejection because the medicament reads on microparticles

without a carrier.

It is noted that the instant claims are drawn to a product, not to a method. Therefore, the intended use of "for allergen-specific immunotherapy capable of generating an immunoprotective response" of claim 15 does not carry patentable weight per se. The claims read on the active or essential ingredients of the composition.

The reference teachings anticipate the claimed invention.

Applicant's arguments filed on 07/21/2008 have been fully considered, but are not found persuasive.

Applicant argues:

> "The disclosures of Nordvall, King and van Toorenbergen are limited to the diagnostic use of particle bound allergens, i.e., the use of bead-bound allergens to measure allergen specific antibodies for diagnostic purposes. However, none disclose or suggest an administrable medicament for allergen-specific immunotherapy and capable of generating an immunoprotective response, the medicament containing a therapeutically effective amount of microparticles comprising: (a) a bead consisting of a three dimensionally cross-linked carbohydrate selected from the group consisting of polyarylamide, vinyl polymer, dextran, agarose, and mixtures thereof; and (b) a polypeptide allergen derived from plant pollen covalently bound to said bead as the present claims require. Accordingly, neither Nordvall et al. nor King et al. nor van Toorenbergen et al. anticipates the invention of claims 10 and 15- 23 as presented herein."

It is the Examiner's position that Nordvall et al. teaches the active or essential ingredients of the medicament composition. The instant claims are drawn to a product, not to a method. Therefore, the intended use of "for allergen-specific immunotherapy capable of generating an immunoprotective response" of claim 15 does not carry patentable weight per se. The

microparticles of Nordvall are not incompatible with pharmaceutical and/or medicinal use, so the claimed medicament is anticipated.

11. Claim 10 stands rejected and claims 15-16 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by King et al. (PTO-892 mailed on 11/13/2007) for the same reasons as set forth in the Office Action mailed on 02/21/2008.

King et al. teaches a medicament containing microparticles comprising Dactylis plomerulata grass pollen (derived from plant and grass pollen) covalently bound to Sepaharose beaded agarose (In particular, abstract, whole document, page 340-341) which is formulated for parenteral application (allergen-bead complex suspended in .1M borate and NaCl) (In particular, page 341, first full paragraph).

It is noted that the instant claims are drawn to a product, not to a method. Therefore, the intended use of "for allergen-specific immunotherapy capable of generating an immunoprotective response" of claim 15 does not carry patentable weight per se. The claims read on the active or essential ingredients of the composition.

The reference teachings anticipate the claimed invention.

Applicant's arguments filed on 07/21/2008 have been fully considered, but are not found persuasive.

Applicant argues:

> "The disclosures of Nordvall, King and van Toorenbergen are limited to the diagnostic use of particle bound allergens, i.e., the use of bead-bound allergens to measure allergen specific antibodies for diagnostic purposes. However, none disclose or suggest an administrable medicament for allergen-specific immunotherapy and capable of generating an immunoprotective response, the medicament containing a therapeutically effective amount of microparticles comprising: (a) a bead consisting of a three dimensionally cross-linked carbohydrate selected from the group consisting of polyarylamide, vinyl polymer, dextran, agarose, and mixtures thereof; and (b) a polypeptide allergen derived from plant pollen covalently bound to said bead as the present claims require. Accordingly, neither Nordvall et al. nor King et al. nor van Toorenbergen et al. anticipates the invention of claims 10 and 15- 23 as presented herein."

It is the Examiner's position that King et al. teaches the active or essential ingredients of the medicament composition. The instant claims are drawn to a product, not to a method. Therefore, the intended use of "for allergen-specific immunotherapy capable of generating an immunoprotective response" of claim 15 does not carry patentable weight per se. The microparticles of King are not incompatible with pharmaceutical and/or medicinal use, so the claimed medicament is anticipated.

12. Claim 10 stands rejected and claims 15-16 are rejected under 35 U.S.C. 102(b) as being anticipated by van Toorenenbergen et al. (PTO-892; Reference U) for the same reasons as set forth in the Office Action mailed on 02/21/2008.

van Toorenenbergen et al. teaches a medicament containing microparticles comprising a tomato pollen allergen (derived from plant pollen) covalently bound to agarose beads which is

formulated for parenteral administration (In particular, abstract, page 248 'IgE antibody measurements section').

It is noted that the instant claims are drawn to a product, not to a method. Therefore, the intended use of "for allergen-specific immunotherapy capable of generating an immunoprotective response" of claim 15 does not carry patentable weight per se. The claims read on the active or essential ingredients of the composition.

The reference teachings anticipate the claimed invention.

Applicant's arguments filed on 07/21/2008 have been fully considered, but are not found persuasive.

Applicant argues:

> "The disclosures of Nordvall, King and van Toorenbergen are limited to the diagnostic use of particle bound allergens, i.e., the use of bead-bound allergens to measure allergen specific antibodies for diagnostic purposes. However, none disclose or suggest an administrable medicament for allergen-specific immunotherapy and capable of generating an immunoprotective response, the medicament containing a therapeutically effective amount of microparticles comprising: (a) a bead consisting of a three dimensionally cross-linked carbohydrate selected from the group consisting of polyarylamide, vinyl polymer, dextran, agarose, and mixtures thereof; and (b) a polypeptide allergen derived from plant pollen covalently bound to said bead as the present claims require. Accordingly, neither Nordvall et al. nor King et al. nor van Toorenbergen et al. anticipates the invention of claims 10 and 15- 23 as presented herein."

It is the Examiner's position that van Toorenbergen et al. teaches the active or essential ingredients of the medicament composition. The instant claims are drawn to a product, not to a method. Therefore, the intended use of "for allergen-specific immunotherapy capable of

generating an immunoprotective response" of claim 15 does not carry patentable weight per se. The microparticles of van Toorenbergen are not incompatible with pharmaceutical and/or medicinal use, so the claimed medicament is anticipated.

13. Claim 10 stands rejected and claims 15-23 are rejected under 35 U.S.C. 102(a) as being anticipated by Gronlund et al. (PTO-892; Reference W) for the same reasons as set forth in the Office Action mailed on 02/21/2008.

Gronlund et al. teaches a 2.1 μm microparticle comprising a) a carbohydrate bead consisting essentially of agarose and b) rPhl p 5b allergen which is covalently bound to the bead, wherein c) the allergen is derived from timothy grass pollen and a medicament for the treatment of the immune system comprising microparticles which is formulated characterized in that it is prepared for parenteral application (In particular, abstract, whole document).

Claims 20 and 23 are included in this rejection because determining the sequence of the reference allergen is merely further characterization of a known compound. Atlas Powder Co. V. IRECO, 51 USPQ2d 1943 (Fed. Cir. 1999)"Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art... However, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer. "The Court further held that "this same reasoning holds true when it is not a property but an ingredient which is inherently contained in the prior art".

The reference teachings anticipate the claimed invention.

Applicant's arguments filed on 07/21/2008 and declaration of Hans Gronlund filed on 07/21/2008 have been fully considered, but are not found persuasive.

Applicant argues:

> "Applicants respectfully submit that this rejection is rendered moot by the cancellation of claims 1-6 and 9 and the amendment of claim 10 to depend from new claim 15 as well as the declaration of Dr. Hans Groenlund provided herewith as Appendix A. In order for a reference to qualify as "prior art" under section 102(a) of 35 U.S.C., it must be by "others". As the instant declaration evidences, the Gronlund et al. publication at issue (i.e., *Immunology*, 107:523-529, 2002) is not a publication by "others" but in fact a publication by the inventors, notwithstanding the inclusion of additional author, Gerhard Dekan. As stated in point 4 of the instant declaration, Gerhard Dekan was merely working under the direction of the present inventors, providing technical assistance, and did not contribute to the conception and/or reduction to practice of the invention disclosed and claimed herein. Thus, in that the Gronlund et al. (Immunology, 2002) publication cited by the Examiner is not in fact "prior art", it cannot serve to anticipate the invention of the pending claims."

It is the Examiner's position that Applicant's arguments and the declaration of Hans Gronlund filed on 07/21/2008 are insufficient to overcome the Gronlund et al. reference. First, the Application Data Sheet lists 'Hans Groenlund' as the author of the instant application, not 'Hans Gronlund' as listed in the Oath and the instant Gronlund reference. Clarification is required. Second, the declaration submitted is sufficient to disqualify Gerhard Dekan as an author of the Gronlund reference. However, the authorship of Gronlund et al. is still by another compared to the inventorship of the instant application because the Gronlund et al. reference does not list John Roennelid and Alex Karlsson-Parra as authors. There must be one to one correspondence between the authorship and the inventorship to disqualify Gronlund et al. as

prior art under 102(a). Therefore, the rejection stands.

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

15. Claims 15 and 18-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over van Toorenbergen et al. (PTO-892, Reference U) in view of Nordvall et al. (IDS filed on 11/13/2007) for the same reasons as set forth in the Office Action mailed on 02/21/2008.

van Toorenbergen et al. and Nordvall et al. have been discussed supra.

The claimed invention differs from the prior art in the recitation of "wherein the allergen is derived from grass pollen" in claim 18 and "wherein the allergen is derived from timothy grass pollen" of claim 19.

It would have been obvious to one of ordinary skill in the art at the time of invention to use the timothy grass pollen allergen of Nordvall et al. in the microparticle of van Toorenbergen et al. because van Toorenenbergen et al. teaches that there is a high incidence of occupational allergy in horiculture and that the microparticles comprising pollen allergens covalently bound to

agarose beads can be used to diagnose allergy to pollen and fruit (In particular, abstract, whole document).

From the reference teachings, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the reference, especially in the absence of evidence to the contrary.

Applicant's arguments filed on 07/21/2008 have been fully considered, but are not found persuasive.

Applicant argues:

"The limitations of Nordvall et al., King et al., and van Toorenbergen et al. are discussed above."

It remains the Examiner's position that it would have been obvious to one of ordinary skill in the art at the time of invention to use the timothy grass pollen allergen of Nordvall et al. in the microparticle of van Toorenbergen et al. because van Toorenenbergen et al. teaches that there is a high incidence of occupational allergy in horiculture and that the microparticles comprising pollen allergens covalently bound to agarose beads can be used to diagnose allergy to pollen and fruit (In particular, abstract, whole document). The references teach the active or essential ingredients of the medicament composition. The instant claims are drawn to a product,

not to a method. Therefore, the intended use of "for allergen-specific immunotherapy capable of generating an immunoprotective response" of claim 15 does not carry patentable weight per se. The microparticles of van Toorenbergen and Nordvall et al. are not incompatible with pharmaceutical and/or medicinal use, so the claimed medicament is obvious.

16. Claims 15 and 21-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over van Toorenbergen et al. (PTO-892 mailed on 02/21/2008, Reference U) , Nordvall et al. (IDS filed on 11/13/2007) or King et al. (IDS filed on 11/13/2007); each in view of Kovacsovics-Bankowskiet al. (PTO-892; Reference V).

Toorenbergen et al., Nordvall et al., King et al., and Gronlund et al. have been discussed supra.

The claimed invention differs from the prior art in the recitation of "wherein the particle size ranges from .1μm to 10 μm" in claim 21 and wherein the particle size ranges from .5 μm to 5 μm" in claim 22.

Kovacsovics-Bankowski et al. teaches that OVA, a known allergen, linked to .5 to 10 μm beads was presented by macrophages with MHC Class I molecules by cells up to 10,000 times more efficiently than soluble OVA alone and primed CTLs in vivo in mice and suggests that this finding may be applied to vaccination strategies in the future (In particular, abstract).

It would have been obvious to one of ordinary skill in the art at the time of invention to use microparticles with size ranges between .5 to 10 μm as taught by Kovacsovics-Bankowski et al. in the microparticles taught by Toorenbergen et al., Nordvall et al., King et al., and Gronlund et al. because Kovacsovics-Bankowski et al. teaches that microparticles under 10 μm enhance MHC presentation of OVA by macrophages.

From the reference teachings, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the reference, especially in the absence of evidence to the contrary.

17. No claim is allowed.

18. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nora M. Rooney whose telephone number is (571) 272-9937.

The examiner can normally be reached Monday through Friday from 8:30 am to 5:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen O'Hara can be reached on (571) 272-0878. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

October 20, 2008

Nora M. Rooney, M.S., J.D.

Patent Examiner

Technology Center 1600

/Maher M. Haddad/
Primary Examiner,
Art Unit 1644